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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,271	10/07/2003	Kenneth G. Powell	7767-192152	3133
26253 75	590 06/03/2005		EXAMINER	
	IGHET, VP AND CHIE	DURAND, PAUL R		
•	BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110		ART UNIT	PAPER NUMBER
FRANKLIN LA	LAKES, NJ 07417-1880		3721	· · · · · · · · · · · · · · · · ·
			DATE MAILED 0//02/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)			
Office Action Summary		10/679,271	POWELL ET AL.			
		Examiner	Art Unit			
		Paul Durand	3721			
Period fo	The MAILING DATE of this communication apported in the plant of the plant is a second of the	pears on the cover sheet with th	e correspondence address			
THE - Exte after - If the - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication, period for reply specified above is less than thirty (30) days, a repl period for reply is specified above, the maximum statutory period in the toreply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply within the set or extended period for reply will, by statutore to reply will, by statutor	136(a). In no event, however, may a reply b ly within the statutory minimum of thirty (30) will apply and will expire SIX (6) MONTHS f s, cause the application to become ABANDO	e timely filed  days will be considered timely.  rom the mailing date of this communication.  DNED (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 18 N	<u>1arch 2005</u> .				
•	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.					
3)	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposit	ion of Claims					
4)🖂	Claim(s) 1-49 is/are pending in the application	<b>).</b>				
	4a) Of the above claim(s) <u>27</u> is/are withdrawn from consideration.					
5)□	Claim(s) is/are allowed.					
6)⊠	☑ Claim(s) <u>1-26 and 28-49</u> is/are rejected.					
-	Claim(s) is/are objected to.					
8)□	Claim(s) are subject to restriction and/or election requirement.					
Applicat	ion Papers					
9)[	The specification is objected to by the Examine	er.				
10)🛛	10)⊠ The drawing(s) filed on <u>07 October 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.					
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
_	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11)	The oath or declaration is objected to by the E.	xaminer. Note the attached Off	ice Action or form PTO-152.			
Priority (	under 35 U.S.C. § 119					
	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Burea	ts have been received. ts have been received in Applic onty documents have been rece	cation No			
* (	See the attached detailed Office action for a list	of the certified copies not rece	eived.			
Ama=1						
Attachmen	n(s) ce of References Cited (PTO-892)	4) Interview Summ	nary (PTO-413)			
2) Notic	ce of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Ma	il Date			
	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date	5) Notice of Inform 6) Other:	al Patent Application (PTO-152)			

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### **DETAILED ACTION**

#### Election/Restrictions

1. Claim 27 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/20/2004.

## "Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1,3,5,8-14,20,28,30,32,35-39,41,43 and 46-49 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Benn (US 4,964,261) in view of White (US 1,931,911).

In regard to claim 1,28 and 39, Benn discloses the invention as claimed including flexible bag 20, with opening by fill tube 27, with a relaxed state volume smaller than a non-relaxed state volume, releasably retaining the bag on scale 21, which allows movement of at least one flexible side, positioning the bag to receive fluid, expanding the bag to a non-relaxed volume in vacuum chamber 22, while subjecting the exterior, interior and the fluid to a predetermined pressure range, dispensing fluid into the container through ports 26 and 27, sealing the container with sealer 23, while the

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container and contents are in a predetermined pressure range, increasing the pressure by removing the vacuum and releasing the container by removing it from the scale (see Figs. 5,6,10-12 and C4,L47 – C5,L5). What Benn does not specifically disclose is the pressure range being greater or equal to the vapor pressure of the liquid. However, it is inherent within Benn to provide a pressure range that is below atmosphere and above the vapor pressure of the particular liquid in order to provide timely filling of the container and to prevent boiling of the liquid during filling. Additionally, it is also inherent that there is a manipulation of the meniscus, which is caused as the pressure is changed when the container is removed to ambient atmosphere pressure.

In the alternative, Whit teaches that it is old and well known in the art of filling containers in a reduced pressure environment to choose a pressure range that is above the vapor pressure of the liquid for the purpose of preventing boil over during filling (see Fig.1 and Pg. 3, L36-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the invention of Benn with the specific pressure range as taught by White for the purpose of preventing boil over during filling.

In regard to claims 3,30 and 41, Benn discloses the invention as claimed including performing the steps in the order recited (see C4,L47 – C5,L5).

In regard to claims 5,32 and 43, Benn discloses the invention as claimed including expanding the container by flexing a flexible element of the bag 20.

In regard to claims 8,35 and 46, Benn discloses the invention as claimed including applying a vacuum to expand the container (see C4,L47 – C5,L5).

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In regard to claims 9,10,14,36,37,47 and 48, Benn discloses the invention as claimed including physical manipulating the flexible element of the bag from a mechanically operated vacuum chamber.

In regard to claim 11, Benn discloses the invention as claimed including where the dispensing step is performed at a location away from the vacuum chamber and the sealing step is performed at the vacuum chamber (see Fig. 10).

In regard to claims 12 and 20, Benn discloses the invention as claimed including placing a dispensing nozzle 2 into a port 26 and filling a container 20 with multiple ports 26 and 27 (see Fig. 10).

In regard to claims 13,38 and 49, Benn discloses the invention as claimed including the inherent manipulation of the meniscus as the flexible component is moved by the pressure changes.

### Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 4,15-19,21,22,31 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benn.

In regard to claims 4,31 and 42, Benn discloses the invention substantially as claimed except for processing some of the steps in a simultaneous manner. However,

the examiner takes Official Notice that it is well known in the art to perform packaging steps in a simultaneous manner for the purpose of increasing manufacturing throughput. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the invention of Benn with simultaneous packaging steps for the purpose of increasing manufacturing throughput.

In regard to claims 15,16,21 and 22, the invention of Benn discloses the invention substantially as claimed except for the flexible component comprising less or more than 2/3 of the package or the volume of the interior of the package. However, it would have been an obvious matter of design choice to provide a package comprised of a flexible component comprising less or more than 2/3 of the package, since applicant has not disclosed that a package comprised flexible component comprising less or more than 2/3 of the package solves any stated problem or is for any particular purpose and it appears the invention would do equally well with the flexible component covering the full package as disclosed by Benn.

In regard to claims 17-19, the invention of Benn discloses the invention substantially as claimed except for the physical material properties of the package. However, it would have been an obvious matter of design choice to provide a package comprised of a hydrophilic, hydrophobic or a wettable surface, since applicant has not disclosed that a package comprised of a hydrophilic, hydrophobic or a wettable surface solves any stated problem or is for any particular purpose and it appears the invention would do equally well with the polymer surface as disclosed by Benn.

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6. Claims 2,6,29,33,40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benn in view of Weiler (US 4,176,153).

In regard to claims 2,29 and 40, Benn discloses the invention substantially as claimed except for packaging in an aseptic environment. However, Weiler teaches that it is old and well known in the art of packaging to fill a container in an aseptic environment for the purpose of preventing contamination during filling (see C1,L18-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the invention of Benn with the aseptic packaging means as taught by Weiler for the purpose of preventing contamination during filling.

In regard to claims 6,33 and 44, Benn discloses the invention substantially as claimed except for expanding the package by injecting gas into the interior. However, Weiler teaches that it is old and well known in the art of packaging to expand a package by injecting a gas into an interior volume for the purpose of opening a package prior to filling (see Figs.1-6 and C2,L49 – C3,L29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the invention of Benn with the expansion means as taught by Weiler for the purpose of opening a package prior to filling.

7. Claims 7,34 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benn and Weiler in view of Shaw (US 3,382,642).

The modified invention of Benn discloses the invention substantially as claimed as applied to claims 1 and 5, 28 and 33, and 39 and 44 above except for the use of a

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inert gas during the packaging process. However, Shaw teaches that it is old and well known in the art of packaging to use an inert gas during packaging for the purpose of increasing the shelf life of a product (see C6,L28-32). Therefore, it would have been obvious to on having ordinary skill in the art at the time the invention was made to have provided the modified invention of Benn with the packaging means as taught by Shaw for the purpose of increasing the shelf life of a product.

8. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benn in view of Green et al (US 5,673,731).

In regard to claims 23 and 26, Benn discloses the invention substantially as claimed as applied to claim 1 above except for a conical opening. However, Green teaches that it is old and well known in the art of packaging to provide a contiguous comical fluid opening 38, with the narrowest point to the inside of container 12 for the purpose of accommodating a fill fitting (see Fig. 3). Therefore, it would have been obvious to on having ordinary skill in the art at the time the invention was made to have provided the modified invention of Weiler with the fill means as taught by Green for the purpose of accommodating a fill fitting.

In regard to claims 24 and 25, Benn discloses the invention substantially as claimed except for the conical fill opening being removable or non-removable.

However, it would have been an obvious matter of design choice to provide a fill opening which is capable of being removable or non-removable, since applicant has not disclosed that a fill opening which is capable of being removable or non-removable solves any stated problem or is for any particular purpose and it appears the invention

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would do equally well with the flexible component covering the full package as disclosed

by Green.

### Response to Arguments

9. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

### Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Durand whose telephone number is 571-272-4459. The examiner can normally be reached on 0730-1800, Monday - Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Durand May 27, 2005

> Stephen F. Gerrity Primary Examiner